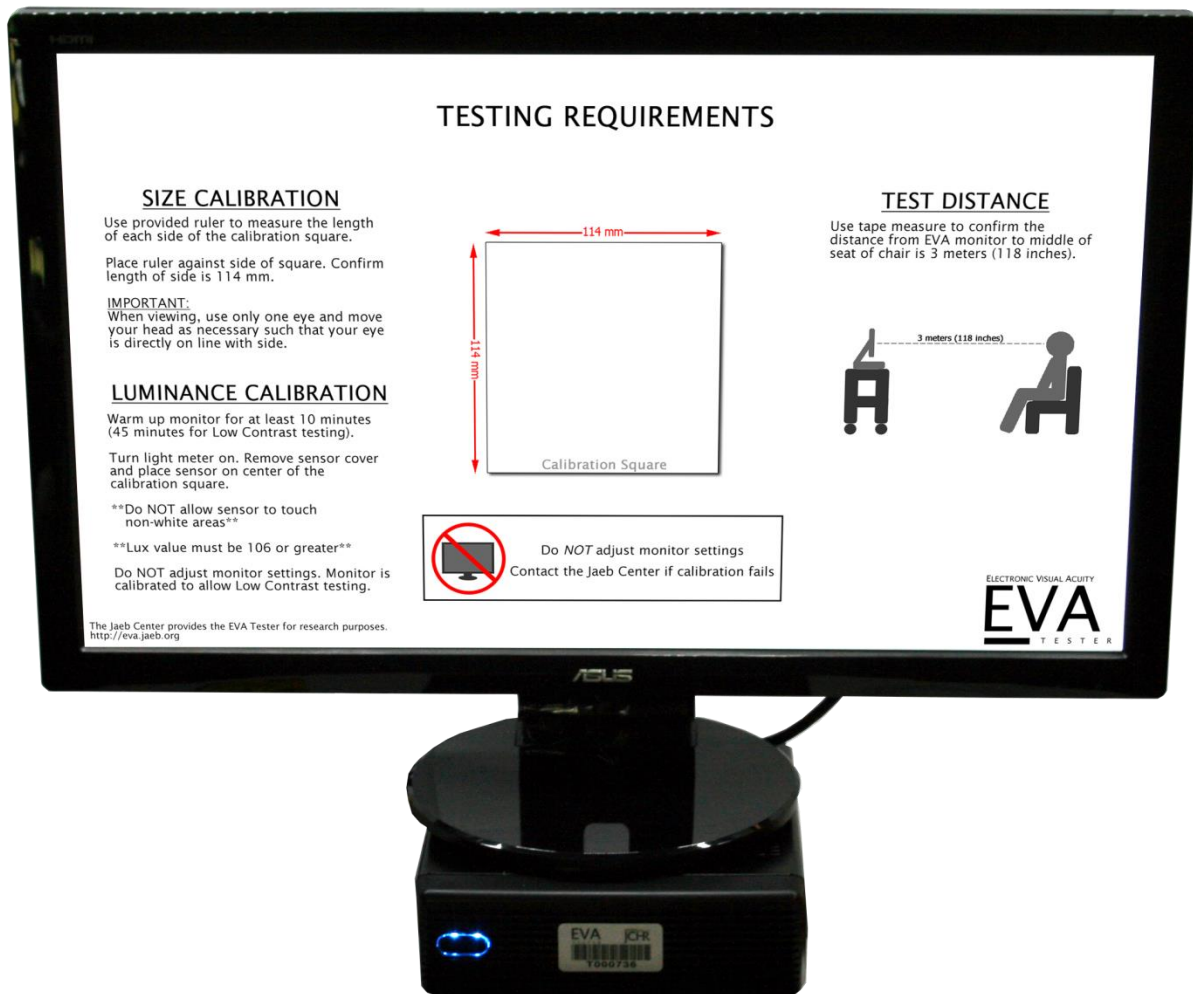


EVA USER'S MANUAL

MODEL 12-WIN



Manual Revised October 2013

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MODEL HIGHLIGHTS

- Model 12-WIN is a desktop EVA Tester that is also configured to display Low Contrast letters.
- Chart application able to display letters down to 20/6.
- E-ETDRS algorithm available in 5% and 2.5% low contrast levels.
- Windows-based system that uses Wi-Fi for communication.
- System controlled using an Apple iPod Touch.
- Sleep option to make monitor dark without turning it off.
- System is only 8 ½" deep and 18" to top of monitor when stacked (monitor is 22" wide).
- Test results are stored as encrypted files per HIPAA requirements.
- Monitor specially configured and calibrated for Low Contrast.

IMPORTANT

A Model 12-WIN EVA Tester is configured and calibrated for low contrast testing. DO NOT adjust the monitor settings. If the monitor does not fall within range (greater than 106 lux on the provided light meter) contact EVA Support at the Jaeb Center.

1. SYSTEM DESCRIPTION

The Electronic Visual Acuity (EVA) Tester uses an Apple iPod Touch to communicate with a Windows-based computer.

For normal (high contrast) testing, stimuli are high-contrast, black letters with luminance of 85 to 105 cd/m² and contrast of 98%. The system can present single letters or lines of letters. Single letters are framed with crowding bars around the letter. For low contrast testing, stimuli are gray letters with a contrast of either 2.5% or 5% compared to the white background. Letters are framed with crowding bars of the same contrast.

For lines of letters in the Chart application, five (5) letters are displayed for sizes smaller than 20/100; a decreasing number of letters is displayed as letter size increases. With a 23.6-inch LCD/LED monitor at 1920 x 1080 pixels, the system is capable of displaying letters from 20/800 (1.6 logMAR) to 20/6 (-0.5 logMAR), at a test distance of 3 meters. Letter size corresponds to the logMAR progression of the ETDRS charts.

The iPod, communicating with the PC wirelessly via Wi-Fi, provides instructions to the technician and displays the letter that is being shown on the monitor. For the automated tests (ATS-HOTV, E-ETDRS) the size and sequence of letter presentations is determined from a computer algorithm based on the subject's responses.

2. DEFINITIONS AND SYSTEM COMPONENTS

2.1 Definitions

EVA PC The personal computer (PC) sent with the EVA Tester. Also referred to as the "Tower."

EVA Tester All components of the EVA Tester including monitor, PC, iPod, programs on the PC, and communication between the iPod and PC.

iPod The Apple iPod Touch that is used as the controller for the EVA Tester.

Program Flash Drive Portable memory device used to start the EVA Tester and store encrypted test results. The flash drive must be inserted in a USB port for the tester to start.

Data Retrieval Flash Drive Flash drive with EVA program to download test data from EVA hard drive when requested by a study coordinating center.

Splash Screen The initial screen when EVA starts up. EVA Testing Requirements are displayed with a white square outlined in black in the middle of the screen. Used for monitor calibration.

Router A wireless-access point used to manage communication between the EVA PC and the iPod.

Tower ID Unique identifier used to configure wireless connection between the iPod and EVA PC. Printed on a label attached to the EVA PC; example "T000001".

Validation Codes Encrypted values for the test result and patient identifier; used during case report form data entry to validate that information is correctly entered.

2.2 System Components

The shipment should include the components listed below:

- EVA PC with Tower ID sticker attached
- EVA PC power adaptor
- 23.6" LED/LCD Monitor
- Monitor power adaptor
- HDMI cable
- Apple iPod Touch
- iPod USB charging cable
- Wireless router
- Router power cord and adaptor
- Ethernet cable
- EVA Program Flash Drive
- Light Meter
- Plastic Ruler
- Tape Measure
- Cart (Optional)

Note: A keyboard and mouse are **not used** with the EVA Tester and are not included.



3. TIPS FOR SUCCESSFUL USE

- Keep the iPod battery charged by reattaching to the USB charging cable plugged into the EVA after each use.
- Use only flash drives with **Model 12-WIN** on the label.
- To shut down the EVA PC, use either the **PC Power** button on the iPod or press and quickly release the power button on the EVA PC. Do NOT press and hold the EVA PC power button or the system may take longer to boot the next time.

4. SYSTEM SETUP

Follow these instructions to set up the 12-WIN EVA Tester.

1. Place the PC and monitor on the cart provided or your own cart.
2. Plug the HDMI cable into the computer and monitor as shown in Figure 2.
3. Plug PC power supply cord into the computer as shown in Figure 1.
4. Connect the iPod to the (white) USB charging cable.
5. Plug Ethernet cable from yellow **LAN** port on Router to the Ethernet port on the back of the EVA PC.
6. Plug Router power cord into back of Router.
7. Plug Monitor, PC, and Router power cords into the power strip and then plug the power strip into a wall outlet.
8. Attach the plastic ruler to the back of the monitor with the Velcro strip.
9. Turn monitor on by pressing power button.
10. Insert the **Model 12-WIN Flash Drive** in USB port as shown in Figure 2.
11. Turn the PC on by pressing the power button on the front of the PC. The computer will go through start up (boot) sequence.
12. When start up is complete, the monitor will display the splash screen with the calibration square in the center.
13. Configure E-ETDRS and ATS-HOTV (MUST be configured before initial use).
 - a. Press the Home button on the iPod (round button below screen).
 - b. The passcode will be the last four digits of the Tower ID. For example, if the Tower ID is T000123, the password will be 0123.
 - c. Tap the EVA icon at the bottom of the screen.
 - d. Tap Configure Studies at the top right of the screen.

- e. Tap **Set E-ETDRS** and check boxes for studies in which your site is participating. Select Non-Study if your EVA Tester is also used for non-study patients.
 - f. Tap **Done**.
 - g. If your site uses ATS-HOTV (for children under age 7), tap **Set ATS-HOTV**, select your studies (and Non-Study if needed), tap **Done**.
 - h. Tap the **Exit** to leave configuration.
14. Confirm testing distance is 3 meters (118 inches) from the patient to the monitor screen.

The EVA Tester is ready to use. Refer to Section 6 for patient testing procedures.

IMPORTANT

A **Model 12-WIN** flash drive is required for this EVA Tester. Usable flash drives are labeled "12-WIN". Do NOT use flash drives intended for other models.

Figure 1
View of the back of the EVA PC



Use for
Program Flash

HDMI

Use for
iPod cable

Use for
Ethernet
cable

Power Cord

Figure 2
View of the back of the Asus monitor



Power Cord

HDMI

5. MONITOR CALIBRATION

The EVA monitor must be correctly calibrated for valid testing. The calibration square is the image displayed on the EVA splash screen. Two monitor calibration checks are performed at regular intervals: (1) size calibration check to confirm letters are accurately displayed and (2) luminance calibration check to confirm the monitor screen is sufficiently bright for testing. Procedures to check calibration on your monitor are as follows:

5.1 Size Calibration

1. Display the EVA splash screen. The outlined square in the middle of the screen is used for size calibration. Each side of the square should be 114 mm in length.
2. Complete the following steps on the top and left side of square:
 - a. Place a ruler with millimeter scale against side of the square. Confirm the length of the side is 114 mm.
IMPORTANT: When viewing, use only one eye and adjust your head as necessary so your eye is directly on line with side.
 - b. If the either side is not 114 mm, contact EVA Support at the Jaeb Center for assistance.

5.2 Luminance Calibration

For correct testing, the white area of the calibration square should be 95 cd/m² (106 lux on the provided light meter), or greater. The corresponding lux values are printed on the light meter label. See Appendix A for instructions and photos.

IMPORTANT!

1. Allow monitor to warm up.
 - a. For regular testing, the monitor should be on for **at least 10 minutes.**
 - b. For Low Contrast testing, the monitor should be on for **at least 45 minutes.**
2. Turn room lights OFF and follow instructions in Appendix A for your light meter.

IMPORTANT

The **Model 12-WIN** EVA Tester has been equipped with a **Sleep** feature that darkens the screen without turning the monitor off. If you use the **Sleep** feature, you do **NOT** need to let the monitor warm up again before use. You should still perform calibration checks before testing.

6. USING THE EVA TESTER

6.1 Perform Visual Acuity Testing

Follow these instructions to perform visual acuity testing with the EVA Tester.

1. Insert the **Model 12-WIN Flash Drive** into a USB port (see Figure 1 on Page 8). Power on the EVA PC.
2. Perform size and luminance calibration checks on the monitor.
3. Confirm test distance is 3 meters (118 inches) from the monitor screen to the position of the patient's face.
4. Confirm florescent lighting is not used in the exam room. Dim incandescent lighting is recommended.
5. Turn iPod on. The iPod screen should display test icons (E-ETDRS, ATS-HOTV, etc.). If the icons are not displayed, tap the **EVA** icon.
6. Tap an icon to start a program.
7. E-ETDRS and ATS-HOTV Testing
 - a. For study patient, select protocol (e.g., DRCRnet, PEDIG, etc.). For non-study patient select Non-Study. Tap **Next**.
 - b. Tap **New Test**.
 - c. Confirm Date and Time are correct. If not, tap **Change Date & Time**, enter the correct date and time and tap **Save Changes**.
 - d. Tap **Next**, verify testing distance and calibration, tap **Next**.
 - e. If a Low Contrast test is being performed, be sure you can see all ten (10) boxes on each of the Low Contrast Calibration screens. If you do not see all 10 boxes, contact the Jaeb center; do not perform low contrast testing. Tap **Next**.
 - f. Follow directions on iPod screen to perform test.

6.2 Validation Codes

The EVA vision test results include encrypted values for the score and patient ID/test date. These codes are displayed on the iPod with the test result and can be used during data entry to confirm the data is entered correctly.

6.3 Viewing a Previous Test

If it is necessary to view the codes for a previous test, select the appropriate icon on the EVA Application screen on the iPod and select the study for which the test was done. Tap **View Previous Tests** and tap either **View by Date** or **View by Patient ID**. Select the appropriate test and the test results, including validation codes, will be displayed.

7. CONFIGURE STUDIES

The Configure Studies program selects studies (or non-study) that will use the E-ETDRS and ATS-HOTV vision testing programs. For example, if a site is participating in the DRCRnet and PEDIG studies, Configure Studies is set to display those studies when E-ETDRS is used.

You must use the Configure Studies program to set up the E-ETDRS and ATS-HOTV programs before initial use.

1. On iPod, tap **Configure Studies** icon in upper right corner.
2. Tap **Set E-ETDRS** and check boxes for studies at your site. Select Non-Study if your EVA Tester is also used for non-study patients.
3. Tap **Done**.
4. If your site uses ATS-HOTV (for children under age 7), tap **Set ATS-HOTV** and repeat steps 2 and 3.
5. Tap **Exit** to leave configuration.

8. RETRIEVE STUDY DATA

Periodically your coordinating center may want to download stored test data from the PC hard drive. They will send you a **Retrieve Data Flash Drive** to download the data and return to the coordinating center.

1. Ensure the EVA Tester is at the Calibration Square.
2. Insert **Retrieve Data Flash Drive** in a USB port. Leave the **Program Flash Drive** plugged in.
3. The data retrieval will start and you will see a message stating that the EVA PC will shut down when the retrieval is complete.
4. When the EVA PC shuts down, remove the **Retrieve Data Flash Drive**.
5. Use the same **Retrieve Data Flash Drive** on each Model 12-WIN EVA Tester at your site, repeating steps 1-4.
6. After retrieving data from all 12-WIN EVA Testers, mail the **Retrieve Data Flash Drive** to your coordinating center. If the files are emailed, include your Project (DRCR, PEDIG, etc.) and Site Number in the subject line.

9. SHUT DOWN THE EVA TESTER

To shut down the EVA PC, use the **PC Power** application on the iPod.

You can also press and quickly release the power button and the PC will safely shut itself down. (Do **NOT** press and hold the power button or system will crash and require several minutes to restart.)

10. EVA VISUAL ACUITY TESTING APPLICATIONS

10.1 E-ETDRS Visual Acuity Test

The Electronic Early Treatment of Diabetic Retinopathy (E-ETDRS) is a visual acuity testing program for subjects 7 years of age or older. It was developed to provide a visual acuity letter score comparable to the ETDRS chart testing score.

The E-ETDRS Visual Acuity Testing protocol consists of an initial screening phase to obtain an approximation of the visual acuity threshold followed by a testing phase to obtain the visual acuity score. Details of the E-ETDRS algorithm and an example are included in Appendix D.

The E-ETDRS application displays the test result as a letter score (number of letters correctly identified) and as a Snellen approximation. Also displayed are validation codes for the test result, patient ID, and test date. These codes can be used to validate correct entry when the data are entered into a case report form.

The **E-ETDRS** application includes study versions for use in specified clinical studies. ***These study versions MUST be used for study patients and patients being screened for the study.*** Data entry of the patient ID and technician ID is required; results are identified by the patient ID and stored on both the Program Flash Drive and on the hard drive.

10.2 ATS-HOTV Visual Acuity Test

The ATS-HOTV is the electronic version of the Amblyopia Treatment Study Visual Acuity Testing protocol that was developed to facilitate the standardization of visual acuity testing in clinical trials of pediatric eye disease involving children in the three to less than 7 years old range.

In brief, the ATS-HOTV consists of the presentation of single-surrounded optotypes (letters H, O, T, and V) in 4 steps: a screening phase, a first threshold determination (Phase I), reinforcement phase, and a second threshold determination (Phase II). Details of the ATS-HOTV algorithm are included in Appendix C.

The ATS-HOTV application displays the test result as a Snellen value. Also displayed are validation codes for the test result, patient ID, and test date. These codes can be used to validate correct entry when the data are entered into a case report form.

The **ATS-HOTV** application includes study versions for use in specified clinical studies. ***These study versions MUST be used for study patients and patients being screened for the study.*** Data entry of the patient ID and technician ID is required; results are identified by the patient ID and stored on both the Program Flash Drive and on the hard drive.

10.3 Low-Contrast E-ETDRS Visual Acuity Test

The Low-Contrast E-ETDRS uses the same algorithm as the E-ETDRS Visual Acuity Test. The Low-Contrast version of the test allows the user to select from two different low contrast levels: 2.5% and 5%. The contrast levels represent the percentage of difference in luminance between the foreground (letter image) and background.

Two Low Contrast Calibration screens are used to check monitor calibration before low contrast testing. The first screen displays a white background with squares that progress from light gray to white. The second screen displays a black background with squares that progress from gray to black. If the monitor's calibration changes, one or more of the squares will not be visible. If that occurs, technicians are advised to contact the Jaeb Center and to not perform any low contrast testing with the system.

10.4 Chart

An application that can be used for manual vision testing. Chart displays individual letters or lines of letters using HOTV or Sloan letters sets. It can also display individual Lea Symbols.

10.5 PC Power

An application to shut down, restart, or "sleep" the EVA PC.

- A. Shutdown – This option turns the EVA PC off. Use this if you want to power off the system or if you need to unplug it.
- B. Restart – This option restarts the EVA PC. You may be asked to do this in the course of troubleshooting.
- C. Sleep – This option displays a black image covering the entire screen. You can use this option when you need to use the room while the EVA Tester is not in use without turning off the EVA PC and/or monitor.

IMPORTANT

The **Model 12-WIN** EVA Tester has been equipped with a **Sleep** feature that darkens the screen without turning the monitor off. If you use the **Sleep** feature, you do **NOT** need to let the monitor warm up again before use. You **should** always perform calibration checks before testing.

11. FREQUENTLY ASKED QUESTIONS

System Questions

1. How much space do I need to properly operate the EVA Tester?
2. Why does the testing distance need to be 3 meters?
3. I have an LCD monitor that didn't come with the EVA Tester; can I use it?
4. Can I use any monitor for Low Contrast testing?
5. Does it matter if the EVA PC and monitor are stacked or separate?
6. Where are the keyboard and mouse?
7. How do I find out which program version my EVA Tester is running?
8. Why do I have to let the monitor warm up? When do I do it?
9. I need to look up a previous score for a patient. How do I do that?

iPod Questions

10. Can I use the Palm PDA from a previous EVA model?
11. What do I do if I cannot find the EVA program on my iPod?
12. My iPod won't communicate with the EVA PC. What do I do?
13. Someone connected my iPod to another Wi-Fi network. How do I get it to work with the EVA Tester again?

System Questions

1. How much space do I need to properly operate the EVA Tester?

The system is calibrated for a 3 meter (118 inches) testing distance from the patient to the front of the monitor screen. Since the base of the monitor has a depth of about 6 inches, you will need approximately 11 feet from the patient to the back of the monitor.

2. Why does the testing distance need to be 3 meters?

For standardized testing of visual acuity in a clinical trial it is best to have the same testing distance at all clinical sites since visual acuity can vary with testing distance. It was therefore decided to have a fixed test distance of 3

meters even if this means that the EVA Tester must be wheeled into position when it is used to test a study patient.

3. I have an LCD monitor that didn't come with the EVA Tester; can I use it?

No. EVA Testers are carefully calibrated and validated with specific hardware. Any variation of this hardware could cause the testing to be invalid.

4. Can I use any monitor for Low Contrast testing?

No. Only the monitor that came with your model 12-WIN EVA Tester can be used for Low Contrast testing. The monitor is part of the system as a whole. The system is carefully calibrated to display the gray levels needed for testing. Using a different monitor would result in different gray levels being displayed and would invalidate any results obtained with that system.

5. Does it matter if the EVA PC and monitor are stacked or separate?

The system will work either way. Choose the setup that is easiest and most comfortable for you. Be sure that you adjust the cart as needed for the correct testing height.

6. Where are the keyboard and mouse?

The EVA Tester does not require a keyboard or a mouse to operate so this equipment is not included. The only equipment required is the PC, the monitor, the router, and the iPod.

7. How do I find out which program version my EVA Tester is running?

The program version for your EVA Tester is located on the bottom of the splash screen. You can also view the version on the iPod by tapping the **Configure Studies** icon; the version is displayed on the bottom of the iPod screen.

8. Why do I have to let the monitor warm up? When do I do it?

All EVA Tester monitors need to warm up to achieve display stability. For high contrast testing, this can be achieved in 10 minutes. For Low Contrast testing, this requires 45 minutes. At that time, the monitor's luminance is stable and all optotypes displayed will be consistent.

The warm-up period should be followed any time the monitor is off for longer than a reboot. If you need to turn the monitor off to make the lane dark for other use, consider using the **Sleep** function found in the **PC Power** menu. You do not need to wait for the warm-up period if the monitor has already warmed up and you used the **Sleep** function.


9. I need to look up a previous score for a patient. How do I do that?

There are two ways to view previous patient test results; by patient and by date. On the iPod, select the appropriate study for the patient, tap **Continue**. Tap **View Previous Tests**. Tap **View by Date** or **View by Patient**. Select the appropriate date or Patient ID for previous results. When completed, tap **Done** three times to exit to the View Previous Tests menu.

iPod Questions**10. Can I use a Palm PDA from a previous EVA model?**

No. The 12-WIN model EVA Tester requires the Apple iPod Touch to access the Wi-Fi signal. PDAs from previous EVA models used Bluetooth to communicate with the PC.

11. What do I do if I cannot find the EVA program on the iPod?

If you cannot find the EVA program, scroll once to the left and type **Safari** in the search bar. Select **Safari** from the list below. In the address bar, type **192.168.250.1** and tap **Go**. Tap the middle button () and then tap **Add to Home Screen**. Name the new icon **EVA**.

12. My iPod won't communicate with the EVA PC. What do I do?

Make sure all cords are plugged in firmly. It may be best to unplug and plug back in all of the cords to ensure a good connection. After checking all cords, reboot the EVA PC by pressing the power button on the front. After the EVA Splash Screen displays, you should be able to connect to the EVA PC. Press the Home button and then tap the EVA icon on the iPod.

Also make sure your iPod is connected to the EVA Tester's network. See the answer below for details.

13. Someone connected my iPod to another Wi-Fi network. How do I get it to work with the EVA Tester again?

Press the Home button, tap **Settings** and tap **Wi-Fi**. There should be a checkmark next to the network named with your EVA Tester's Tower ID (e.g. T000123). If you have connected the iPod to another network, you will need to tap the blue arrow at the right side of the screen, and tap **Forget this network**. Once you have done that, go to the previous screen and find your Tower ID in the list of networks. Tap on it and the iPod will join the network. Press the Home button and tap the EVA icon to begin using the EVA Tester.

APPENDIX A Light Meter Instructions

The light meter is used to calibrate the computer monitor that you use for visual acuity determinations.

*** CRITICAL NOTE ***

Effective May 2012, EVA Testers should only use a **digital** light meter. See below for photographs and instructions to identify and correctly use your meter.

YOU MUST USE THE CORRECT PROCEDURE FOR VALID TEST RESULTS!

DIGITAL LIGHT METER Mastech LX1330B

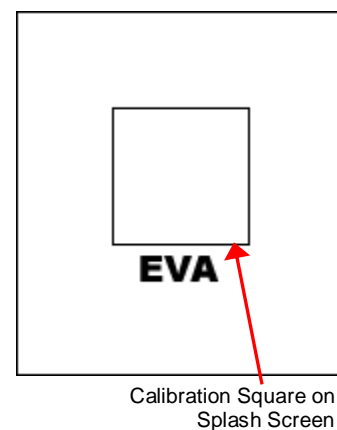
Important:

- Your EVA Tester **MUST** display the calibration image with a white square inside a black frame as shown at right. If you do not have this image, contact your coordinating center. Do NOT continue with calibration.
- Allow monitor to warm up for **at least 10 minutes**.
- Be sure other lights are off in the room when you take light meter readings.

Procedure

Confirm that all other lights are off in the room.

1. **Confirm monitor has been warming up for at least 10 minutes.**
2. Display the EVA splash screen.
3. Turn the light meter on by pressing the **POWER** button. If battery icon is displayed on the LCD screen, replace the 9V battery.
4. Confirm the light meter screen displays only the word "Lux" (on bottom right). If other items are displayed turn the meter off then on again to clear the display.



5. Press the **Range** button once.
 6. Remove the sensor protective cover and place the side with the white circle (see image above) on the white area in the center of the EVA calibration square. Do NOT allow the sensor to touch non-white areas.
 7. The display will return the lux value of the monitor screen. Confirm that the displayed value falls within the range specified on your light meter label.
If the displayed value is below the specified range, increase brightness, leave the monitor on for 10 minutes, and then recheck with the light meter (recommend increasing brightness in 5% increments).
 8. When finished with light meter calibration, replace the protective cover to avoid damage when not in use.
-

APPENDIX B
iPod Diagram
Apple iPod Touch 5G 16GB



APPENDIX C

ATS-HOTV© Visual Acuity Test Protocol

Single letters with surround bars $\frac{1}{2}$ letter width from the letter are presented in four phases: screening, phase I (first threshold determination), reinforcement, and phase II (second threshold determination).

- In phase I and phase II, up to four single letters are sequentially presented at each logMAR level* that is tested.
- A level is considered to be 'passed' if 3 of 3 or 3 of 4 letters are correct and 'failed' if 2 letters at a level are missed.
- Testing of a level stops as soon as criteria are met for either 'pass' or 'fail'.

Screening Phase

Starting from either 20/100 or 20/400, single letters, in sequential descending logMAR sizes, are shown until one is missed.

1. Tester selects 20/100 or 20/400 size letter to present as starting point (depending on the expectation of visual acuity level based on previous testing or a pretest).
2. If response is correct, letter at next smallest logMAR level is presented and testing continues sequentially with one letter per logMAR level through 20/20 until there is an incorrect response.
3. If starting point was 20/100 and response is incorrect at either 20/100 or 20/80, screening is restarted at 20/400.
4. If starting point is 20/400 and response is incorrect at either 20/400 or 20/320, screening is restarted at 20/800.
 - If 20/800 is missed, 20/800 becomes the starting level for phase I.

Phase I

Starting 2 logMAR levels above the missed level in Screening, the smallest logMAR level at which 3 of 3 or 3 of 4 letters are correctly identified is determined.

1. Up to 4 single letters are sequentially presented 2 logMAR levels above the level missed in screening
 - Exception: if 20/20 was correct in Screening, phase I starts at 20/30.
 - Exception: if 20/800 or 20/640 was missed in Screening, phase I starts at 20/800
2. If first tested level is failed, testing continues at sequentially larger logMAR levels until a level is passed.
 - If 20/800 is failed, phase I ends, the Reinforcement phase is omitted, and 20/800 is retested in phase II
3. If first tested level is passed, testing continues at sequentially smaller logMAR levels until a level is failed.

Reinforcement Phase

In order to get the child whose attention is drifting back on track, 3 letters larger than the phase I threshold are sequentially presented.

1. Starting 3 levels larger than the level missed in phase I, 3 successively smaller single letters are presented.
 - Exception: if the level failed in phase I is 20/500 or 20/640, 3 20/800 letters are shown for reinforcement
 - Note: the reinforcement phase responses do not contribute to the visual acuity score and even if the responses are incorrect, the test proceeds to phase II.

Phase II

The last level missed in Phase I is retested and if 'passed', testing continues until a level is 'failed'

1. Up to 4 single letters are sequentially presented at the last level missed in phase I
2. If the level is failed, testing stops.
3. If the level is passed, testing continues at sequentially smaller logMAR levels until a level is failed.

Final Visual Acuity Score

The visual acuity score is the smallest logMAR level passed in Phase I or Phase II.

*logMAR levels (Snellen equivalents): 20/800, 20/640, 20/500, 20/400, 20/320, 20/250, 20/200, 20/160, 20/125, 20/100, 20/80, 20/63, 20/50, 20/40, 20/32, 20/25, 20/20, 20/16, 20/12

APPENDIX D

E-ETDRS© Test Protocol

The EVA runs a visual acuity testing program called E-ETDRS© (Electronic Early Treatment of Diabetic Retinopathy). The program has been developed to provide a visual acuity letter score that is comparable to the ETDRS chart testing score.

During development of the E-ETDRS protocol, a study was conducted in which high validity and test-retest reliability were demonstrated (*Mokey PS, Turpin AH, Beck RW et al. A computerized method of visual acuity testing: adaptation of the amblyopia treatment study visual acuity testing protocol. Am J Ophthalmol 2001; 132:903-14*).

Overview

The E-ETDRS Visual Acuity Testing Protocol consists of an initial screening phase to obtain an approximation of the visual acuity threshold and then a testing phase to obtain the visual acuity score.

The protocol is summarized below. The complete algorithm is depicted in the figure that follows. Letters are displayed with surround bars one full letter width from the letter.

The E-ETDRS testing protocol:

<u>Screening phase:</u>	With single letter presentations, determines smallest logMAR level at which a letter is correctly identified.
<u>Testing phase:</u>	Starts testing letters by intermixing letter sizes of screening phase score and one level smaller.
<u>Test progress:</u>	If a letter is missed at a level, one level larger is added to the testing mix; if a letter is correct at a level, one level smaller is added to the testing mix.
<u>Acuity determination:</u>	Tests 5 letters at each level until smallest level with 5/5 correct and the smallest level with 0/5 correct are determined.

Example:

IN THE FOLLOWING EXAMPLE, C = CORRECT AND M = MISSED

Screening: 20/400c, 20/200c, 20/100c, 20/50c, 20/25m, 20/40m Score = 20/50

Test progress

1. Start by intermixing 20/50 and 20/40 letters: 20/50c, 20/40m, 20/50c, 20/40m, 20/50m
2. Because a 20/50 letter was missed, add 20/63 to the letter mix (so now have letters of 20/40, 20/50, and 20/63 intermixed): 20/63c, 20/50c, 20/40c
3. Because 20/40 was correct, add 20/32 to the letter mix (mix is now 20/32, 20/40, 20/50, and 20/63): 20/32m, 20/63c, 20/63c, 20/50m
4. Five letters at 20/50 have been tested, so it drops out of the mix (mix is now 20/32, 20/40, and 20/63): 20/63c, 20/40c, 20/32m, 20/40m
5. Five letters at 20/40 have been tested, so it drops out of the mix (mix is now 20/32 and 20/63): 20/32m, 20/32m, 20/63c
6. Five letters at 20/63 have been tested, so it drops out of the mix (mix is now 20/32 only): 20/32m
7. Five letters at 20/32 have been tested; there are no letters left in the mix so test is over

Test summary

20/63 5/5 correct
 20/50 3/5 correct
 20/40 2/5 correct
 20/32 0/5 correct

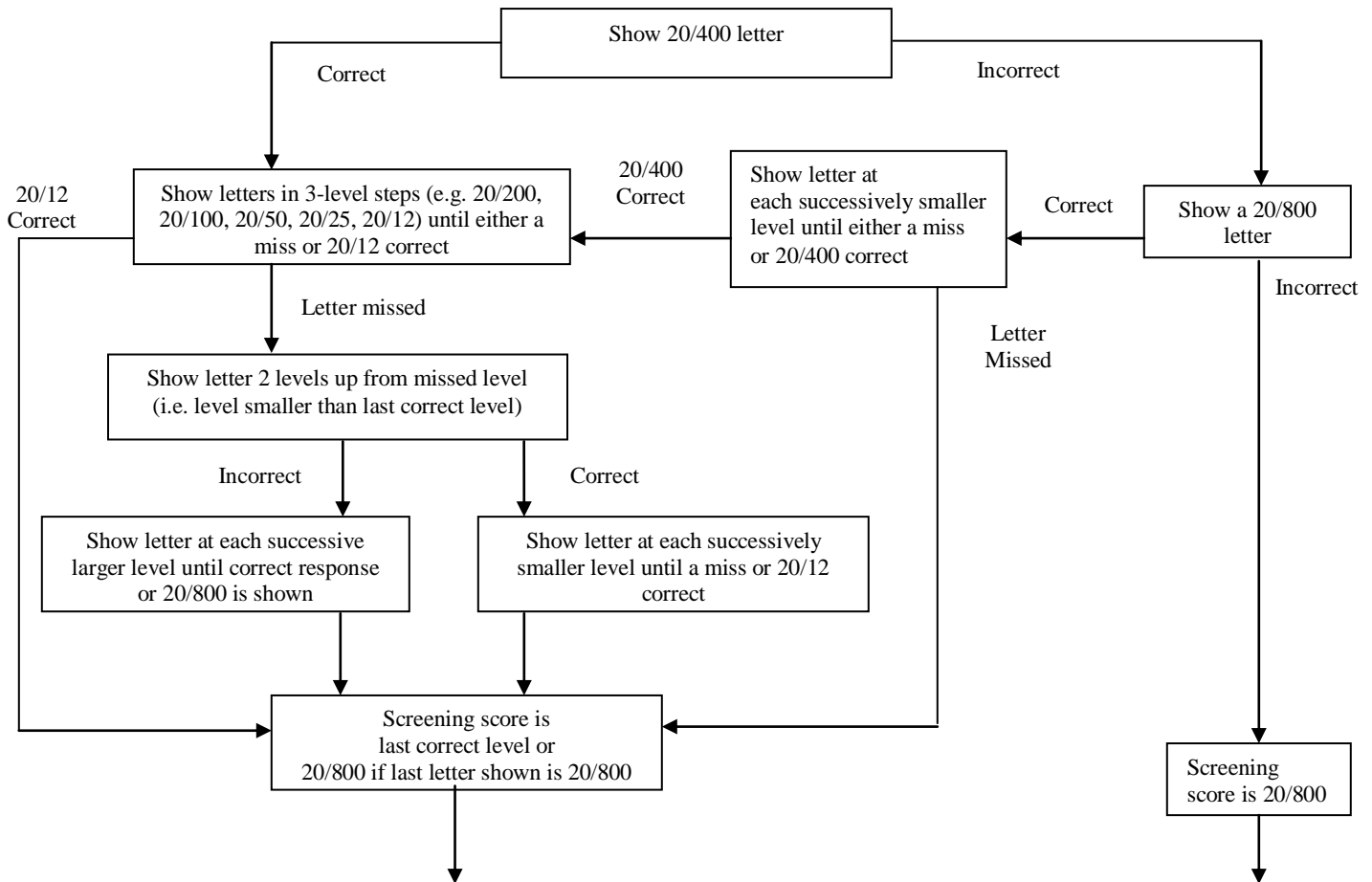
Letter Score: 10 (number of letters correctly identified)
 + 55 (5 times the number of lines above (larger than) 20/63 and through 20/800)
 = 65

Snellen Approximation (logMar to Snellen conversion for 65 letters): 20/50

Electronic ETDRS (E-ETDRS) Visual Acuity Testing Protocol Algorithm

Screening Phase

In each step, one letter is shown at each logMAR level.



Threshold Phase

- To start, the letter pool consists of letters from 2 levels*: the level of the screening phase score and one level smaller.
- Each letter presentation is randomly selected from the active pool of letters with the stipulation that every third letter must be from the largest level in the active letter pool.
- A level remains in the active pool until 5 letters are tested at the level.
- A new level is added to the active letter pool when:
 - A letter from the largest level in the pool is missed: one level larger is added to the letter pool†
 - A letter from the smallest level in the pool is correct: one level smaller is added to the letter pool‡
- Testing continues until an upper logMAR level with 5 of 5 letters correct and a lower logMAR level with 0 of 5 letters correct are determined and 5 letters are tested on all levels in between the upper and lower logMAR levels.§
- Visual acuity score is the number of letters correctly identified during threshold testing, plus 5 letters for each logMAR line above the upper logMAR level through 20/800.

The screening phase uses the letters V, R, K and D. The threshold phase uses the same 5 letters from the Sloan letter set that appear on the original ETDRS charts for right and left eyes.

*Unless screening score was 20/12, in which case letter pool consists of only 20/12 letters.

†Unless 20/800 letter is missed.

‡Unless 20/10 is correct.

§If 20/10 becomes part of the active letter pool, it will be the lower logMAR level.